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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,012	DE LAS HERRERIAS ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-9, 18-19, 21, and 25-26 in the reply filed on 6/23/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of SEQ ID NOS: 17 and truncated peptides SEQ ID NOS: 29-36, in the reply filed on 6/23/08 is acknowledged. The traversal is on the ground(s) that SEQ ID NOS: 1-6, 9-14, 16-22, and 24-28 should also be examined. SEQ ID NOS: 24-28 are truncated peptides of SEQ ID NO: 17 and will be rejoined. SEQ ID NOS: 1-6, 9-14, and 16-22 will not be rejoined. They do not share a special technical feature with SEQ ID NOS: 17 and 24-36. Applicant's arguments are not persuasive. The common structural feature argued by applicant is not disclosed in the specification nor set forth in the claims. The functional attribute argued by applicant is not a special technical feature as evidenced by the search report and IPER of record. Inhibitory peptides of TGF-β1 would have been known in the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-15, 17, 20, 22-24, and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/23/08.

Claims 1-9, 18-19, 21, and 25-26 have been examined with respect to SEQ ID NOS: 17 and 24-36. All other sequences recited in the claims are withdrawn from further consideration

pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/23/08.

Claim Objections

Claim 21 is objected to because of the following informalities: The claim does not end in a period (“.”). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 18-19, 21, and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claims 1-9 have been substantively amended and claims 18-19, 21, and 25-26 are newly introduced claims. (See 2/21/06 preliminary amendment.) No basis has been pointed to for these changes and new claims and none is apparent.

Claim 1 as amended includes truncations of one or two amino acids whereas the original claim recited fragments comprising 3 to 15 amino acids.

Claim 2 as amended does not require a biological activity whereas the original claim recited inhibition of TGF-β1 *in vitro* and/or *in vivo*. New claim 26 adds this activity.

Claims 5-7 were originally in "Use of a peptide..." claim format. As amended they are directed to methods of making a pharmaceutical composition for a particular condition. These methods do not appear to be contemplated. Furthermore, these claims do not further limit the subject matter of claim 4. They do not provide further limitations on the steps for making the pharmaceutical composition (i.e. introducing the peptide of claim1 into a pharmaceutically acceptable carrier). They do not further limit the peptide or carrier required by the pharmaceutical composition.

Claim 8 originally was directed to a pharmaceutical composition that included at least one pharmaceutically acceptable excipient. As amended there is no excipient. New claim 21 adds a pharmaceutically acceptable excipient. The specification does not appear to contemplate the composition of claim 8 in the absence of a pharmaceutically acceptable excipient.

Claim 9 as amended is directed to a composition comprising the peptide of claim 8 in addition to neutralizing antibodies, antisense oligonucleotide sequences, and/or soluble receptors. The specification does not appear to contemplate such compositions.

Claim 18 is a new claim and recites the "SEQ ID NO: 17 peptide is truncated up to five amino acids from C terminal end." The specification does not appear to contemplate this generic concept. SEQ ID NOS: 33 and 34 (see claim 19) have C-terminal truncations of SEQ ID NO: 17; however, these particular embodiments do not provide basis for the generic concept claimed. See also claim 25 which also recites the peptide is truncated up to five amino acids from C terminal end.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is directed to methods of making a pharmaceutical composition. Claims 5-7 are confusing because they do not provide further limitations to the steps for making the pharmaceutical composition (i.e. introducing the peptide of claim1 into a pharmaceutically acceptable carrier). They do not further limit the peptide or carrier required by the pharmaceutical composition. Clarification is requested.

Claim 7 recites "hepatic fibrosis (cirrhosis)." It is unclear if the claim is limited to"cirrhosis" or embraces other forms of hepatic fibrosis. The parentheses are confusing in determining the scope of the claim.

Claim 8 does not further limit the peptide of claim 1. The preamble recitation of "pharmaceutical composition" does not provide any further characteristics or limitations. Both claim 1 and claim 8 require only a peptide that binds to TGF-β1.

Conclusion

SEQ ID NO: 17 is a synthetic peptide and is not naturally occurring. SEQ ID NOS: 24-36 are different truncated forms of SEQ ID NO: 17. The prior art of record does not disclose nor suggest the structure of any of these peptides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa